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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Shannon Gomez, Plaintiff, v. American Medical Systems Incorporated, Defendant.	No. CV-20-00393-PHX-ROS **ORDER**

Pending before the Court are eight *Daubert* motions. Defendant American Medical Systems ("AMS") filed motions seeking to exclude the general causation opinions of Dr. Bruce Rosenzweig (Doc. 104), the specific causation opinions of Dr. Bruce Rosenzweig (Doc. 61), the expert opinions of Dr. Vladimir Iakovlev (Doc. 67), the specific causation opinions of Dr. Jerry Blaivas (Docs. 72), and the expert opinions of Drs. Scott Guelcher and Jimmy Mays (Doc. 74). Plaintiff Shannon Gomez ("Gomez") filed motions seeking to exclude the expert opinions of Dr. Debora L. Joslin (Doc. 70), Dr. Karen Becker (Doc. 106), and Dr. Stephen F. Badylak (Doc. 107).

For the reasons below, the motion concerning Dr. Rosenzweig's general causation opinions will be granted in part and denied in part; the motion concerning Dr. Rosenzweig's specific causation opinions will be denied; the motion concerning Dr. Iakovlev's expert opinions will be granted; the motion concerning Dr. Blaivas's specific causation opinions will be denied; the motion concerning Drs. Guelcher and Mays' expert opinions will be granted in part and denied in part; the motion concerning Dr. Joslin's

expert opinions will be denied; the motion concerning Dr. Becker's expert opinions will be denied; and the motion concerning Dr. Badylak's expert opinions will be denied. The Court will then set this matter for trial.

BACKGROUND

This case originated in one of seven multidistrict litigations ("MDLs"), totaling more than 100,000 cases, concerning products liability for pelvic repair systems, that is, vaginal mesh. (Doc. 52 at 1). All MDL cases were initially before Judge Joseph R. Goodwin in the Southern District of West Virginia.[1] Plaintiff Shannon Gomez filed her Amended Short Form Complaint on June 28, 2013 alleging, as a result of the implantation of two American Medical Systems ("AMS") vaginal mesh products, negligence; gross negligence; design defect; manufacturing defect; failure to warn; defective product; breach of express warranty; breach of implied warranty; violation of consumer protection laws; fraudulent concealment; constructive fraud; discovery rule, tolling and fraudulent concealment; negligent misrepresentation; negligent infliction of emotional distress; unjust enrichment; and punitive damages. (Doc. 17).

While in the MDL phase, fact and expert discovery was completed. (Doc. 52 at 1). The parties also were required to file dispositive and *Daubert* motions. (Doc. 52 at 1). In Pretrial Order #255, Judge Goodwin set October 18, 2018 as the deadline for *Daubert* motions. (Doc. 35). AMS filed four timely *Daubert* motions challenging the opinions and testimony of Dr. Bruce Rosenzweig; Dr. Jerry Blaivas; Dr. Vladimir Iakovlev; and Drs. Scott Guelcher and Jimmy Mays. (Docs. 58-6 at 1; 58-18 at 1; 58-21 at 1; 58-31 at 1). On November 9, 2018, Gomez filed her own *Daubert* motion, seeking to exclude the testimony of Dr. Debora L. Joslin. (Doc. 58-11 at 1–2). On November 16, 2018, AMS moved to strike Gomez's *Daubert* motion as untimely. (Doc. 58-16 at 1). In AMS's Motion to Strike, AMS also responded to the merits of Gomez's motion regarding Dr. Joslin. (Doc. 92 at 3–8). Gomez never responded to AMS's Motion to Strike nor replied to AMS's argument on the merits. The *Daubert* motions were not resolved by Judge Goodwin.

[1] In prior MDL cases, Judge Goodwin ruled on *Daubert* motions regarding some of the experts in this case. If applicable, the Court will rely on Judge Goodwin's prior rulings.

This case was eventually transferred to the District of Arizona. In the order transferring the case, Judge Goodwin ordered the parties to designate relevant documents from the MDL in order to constitute an appropriate record for this Court. (Doc. 52 at 2). On February 19, 2020, parties filed the Joint Designation of Record for MDL Transfers. (Doc. 53). In it, Gomez included a Notice of Adoption, purporting to adopt prior *Daubert* motions filed in separate cases for some of AMS' experts (Dr. Stephen Badylak, Dr. Karen Becker, Adam Kozak, and Dr. James Coad). (Docs. 53 at 3; 81 at 3). The Notice of Adoption did not cite specific prior motions but claimed to "hereby adopt and incorporate by reference all prior Daubert Motions filed in this MDL and related MDLs" for the four witnesses. (Doc. 53-35 at 1). Additionally, the Notice of Adoption was filed in a later "wave" of cases in the AMS MDL, not the "wave" that included Gomez's case.[2] (Doc. 53-35 at 1).

On February 20, 2020, the case was transferred to the District of Arizona. (Doc. 52 at 2). And Judge Diane J. Humetewa ordered the parties to "refile *Daubert* motions to only include factual information relevant to this Plaintiff and not other plaintiffs who are not present in this case" by March 20, 2020. (Docs. 56; 60). On March 20, 2020, AMS filed its four *Daubert* motions and Gomez filed three motions. (Docs. 61; 67; 72; 74). Gomez filed responses to each of the four motions, and AMS failed to file replies.[3] (Docs. 80; 82; 83; 84).

In support of her motions, Gomez filed a variety of briefs taken from other MDLs concerning different mesh products and manufacturers. Although the defendants in the other MDLs relied on the same experts, the experts submitted different reports in each MDL. Gomez filed three separate briefs[4] regarding a single witness, Dr. Badylak, and a

[2] The MDL has consisted of numerous "waves" of cases. Each "wave" is virtually its own MDL with motions and orders that only apply to parties in that "wave." Later "waves" sometimes adopted motions from earlier "waves" to preserve legal resources. Here, however, Gomez attempts to include a Notice of Adoption from Wave 5 when Gomez's case was included in Wave 3 of the MDL. (Docs. 53 at 1; 35 at 1).

[3] AMS filed at least three replies in the MDL court but failed to refile the replies in this Court. (Docs. 58-9; 58-30; 58-34).

[4] Two of the briefs were taken from a separate MDL and one from an early "Bellwether" case in this MDL, which featured an expert report not relevant to this case.

brief taken from a separate MDL regarding Dr. Becker. In short, Gomez paid little attention to what she was filing and disregarded the order requiring the motions be updated to reflect information specifically relevant to this case.

On April 3, 2020, AMS filed a Motion to Strike the *Daubert* motions related to Dr. Badylak and Dr. Becker. (Doc. 81). On August 31, 2020, AMS filed the Motion to Strike the Dr. Joslin *Daubert* motion. (Doc. 91). Consistent with the motion to strike filed at the MDL phase, the motion included a response on the merits of Gomez' motion to exclude Dr. Joslin. (Doc. 92 at 3–8). Gomez never responded to AMS's Motion to Strike regarding Dr. Joslin nor replied to AMS's argument on the merits.

On September 1, 2020, this case was reassigned from Judge Humetewa to this Court. (Doc. 93). And on December 11, 2020, the Court granted AMS's Motion to Strike Gomez's irrelevant *Daubert* motions for Dr. Badylak and Dr. Becker. (Doc. 94). The Court denied AMS's Motion to Strike Gomez's *Daubert* motion for Dr. Joslin and construed AMS's motion as a response to the original *Daubert* motion. (Doc. 94). The Court allowed Gomez to file new, relevant *Daubert* motions for Dr. Badylak and Dr. Becker, and the Court also ordered all parties to file all papers, including missing replies, relevant to the pending *Daubert* motions. (Doc. 94). Because both parties had failed to adhere to previous Court Orders and rules, the Court instructed the parties shall "strictly comply with all Local and Federal Rules as well as the Orders of this Court." (Doc. 94 at 6). The Court warned the parties, that "[f]ailure to comply with all orders, rules, and procedures will result in sanctions, which may include granting or denying motions, dismissal of claims or defenses, default judgment, or awards of attorneys' fees." (Doc. 94 at 6).

On December 18, 2020, AMS filed four replies to *Daubert* motions and a motion for leave to file another *Daubert* motion that had been filed at the MDL phase but had not been refiled in this Court. (Docs. 95–99). The same day, Gomez filed a motion for extension of time to file the new *Daubert* motions. (Doc. 100). The Court granted AMS's motion for leave to file and Gomez's motion for an extension of time. (Doc. 101).

On January 4, 2021, AMS filed a motion followed by an amended motion to limit the general causation opinions and testimony of Bruce Rosenzweig, MD. (Docs. 102, 104).

Because Gomez failed to respond, the motion was granted as unopposed. (Doc. 113). Gomez then filed a motion to vacate the order granting the unopposed motion. (Doc. 114). That motion to vacate was granted, proper papers were filed, and all pending *Daubert* motions are now fully briefed.[5] (Doc. 119).

ANALYSIS

Expert testimony is governed by Federal Rule of Evidence 702, 703, and *Daubert* and its progeny. *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 592 (1993). The first inquiry asks whether a witness is qualified as an expert. Fed. R. Evid. 702. An expert is qualified by "knowledge, skill, experience, training, or education." *Id.* This is not to be construed in a "narrow sense." *Id.* Advisory Committee's note to 1972 Proposed Rules (explaining the Rule includes "skilled" witnesses, such as a landowner testifying to land values, as an expert and is not limited to those with formal credentials); *see also Thomas v. Newton Int'l*, 42 F.3d 1266, 1269–70 (9th Cir. 1994) (holding a longshoreman with 29 years of experience was an expert as to the working conditions of longshore personnel). "Ordinarily, courts impose no requirement that an expert be a specialist in a given field, although there may be a requirement that he or she be of a certain profession, such as a doctor." *Doe v. Cutter Biological, a Div. of Miles Labs.*, 971 F.2d 375, 385 (9th Cir. 1992). "[L]ack of particularized expertise goes to the weight accorded her testimony, not to the admissibility of her opinion as an expert." *United States v. Garcia*, 7 F.3d 885, 890 (9th Cir. 1993).

Courts then conduct a two-step inquiry. *Daubert*, 509 U.S. at 592. First, does the testimony amount to scientific knowledge? *Id.* Second, is the knowledge relevant or does it assist the trier in understanding or determining a fact in issue? *Id.* If so, the testimony is admissible. *Id.* To be scientific knowledge, the testimony must be based on sufficient facts or data. Fed. R. Evid. 702(b). And the testimony must be the product of reliable principles and methods, which in turn must be reliably applied to the facts of the case. Fed. R. Evid.

[5] The Court sanctioned Gomez's counsel and required him to reimburse AMS's reasonable attorneys' costs and fees incurred in litigating the motion to vacate. (Doc. 119). Separately, Gomez failed to file a reply to her *Daubert* motion regarding Dr. Joslin. The Court will rule on the motion nonetheless.

702(c)–(d). The non-exhaustive factors to determine whether testimony is valid scientific knowledge include "(1) whether the expert's technique or theory can be or has been tested—that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reasonably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community." Fed. R. Evid. 702 Advisory Committee's note to 2000 amendments. Not every factor is relevant to reliability in every case and the significance of each factor is case-dependent. *Murray v. S. Route Mar. SA*, 870 F.3d 915, 924 (9th Cir. 2017). "District courts have broad range to structure the reliability inquiry and may choose not to comment on factors that would not inform the analysis." *Id.* For example, where there is an absence of peer-reviewed studies, an expert may proffer a diagnostic hypothesis "so long as [the expert] relied upon a variety of objective, verifiable evidence." *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1060–61 (9th Cir. 2003), *as amended on denial of reh'g* (Sept. 25, 2003) (internal quotation and citation omitted). "It is well-established that expert testimony concerning an ultimate issue is not per se improper." *Hangarter v. Provident Life & Acc. Ins.*, 373 F.3d 998, 1016 (9th Cir. 2004) (internal quotations and citation omitted). "That said, an expert witness cannot give an opinion as to her legal conclusion, i.e., an opinion on an ultimate issue of law." *Id.* (internal quotations and citation omitted). The party offering the expert testimony must establish it as qualified and reliable by a preponderance of the evidence. *Daubert*, 509 U.S. at 593 n.10.

I. Dr. Bruce Rosenzweig's General Causation Opinions

AMS seeks to exclude Dr. Bruce Rosenzweig's general causation opinions. (Docs. 104; 61). Dr. Rosenzweig is a urogynecologist, who has provided causation opinions in a number of AMS MDL cases. (Doc. 105 at 2). Here, he provides general causation opinions related to AMS's Monarc and Miniarc products, both of which were implanted here, and

specific causation opinions related to Gomez's medical records. (Docs. 105 at 2; 65 at 1).

A. Corporate Conduct, Knowledge, and State of Mind

AMS seeks to exclude Dr. Rosenzweig's opinions about AMS's corporate conduct, knowledge, and state of mind. Regarding AMS's conduct, AMS argues Dr. Rosenzweig "merely repeat[s] language from AMS (or other company) documents" in his expert reports. (Doc. 105 at 3). AMS complains Dr. Rosenzweig "quotes company documents at length, at times even reproducing them wholesale." (Doc. 105 at 3). Gomez acknowledges Judge Goodwin's "prior orders precluding experts from providing narrative summaries" of corporate conduct as unhelpful to the jury. (Doc. 120 at 12). But Gomez argues Dr. Rosenzweig relies on these documents in forming his opinion that AMS should have provided more information to physicians and patients so they could make an informed decision about the mesh. (Doc. 120 at 12).

With regard to Dr. Rosenzweig's expert report in a different manufacturer's vaginal mesh litigation, Judge Goodwin reasoned, "a narrative review of corporate documents . . . is not helpful to the jury." *Huskey v. Ethicon*, 29 F. Supp. 3d 691, 706 (S.D.W. Va. 2014). Other courts have held similarly, "an expert cannot be presented to the jury solely for the purpose of constructing a factual narrative based upon record evidence" *Johns v. Bayer Corp.*, No. 09CV1935 AJB DHB, 2013 WL 1498965, at *28 (S.D. Cal. Apr. 10, 2013) (citation and internal quotation marks omitted); *see also id.* (citing *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 551 (S.D.N.Y.2004)) ("rejecting portions of plaintiffs' expert's testimony that was 'a narrative reciting selected regulatory events' because '[s]uch material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence'").

As Judge Goodwin recognized, "an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Tyree v.*

Bos. Sci. Corp., 54 F. Supp. 3d 501, 517–18 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014). The Court agrees an expert may not testify to corporate conduct but notes AMS's documents may otherwise be admissible.

Regarding state of mind opinions, AMS provides a sampling offered by Dr. Rosenzweig in his expert report:

> That a supplier of the resin used for AMS's mesh "was unaware" that the resin was being used in pelvic mesh devices.
>
> That AMS "knew or should have known that polypropylene mesh is not inert and is subject to degradation inside the body.
>
> That AMS "knew" that mesh could degrade, could "shrink in vivo," and had insufficient pore size.

(Doc. 105 at 3).

Courts have repeatedly recognized "the opinions of expert witnesses on the intent, motives, or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or expertise." *See, e.g.*, *Aya Healthcare Servs. v. AMN Healthcare*, No. 17CV205-MMA (MDD), 2020 WL 2553181, at *5 (S.D. Cal. May 20, 2020) (citations and internal quotation marks omitted); *see also In re Bos. Sci. Corp. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2326, 2018 WL 2426159, at *2 (S.D.W. Va. May 29, 2018).

Judge Goodwin held similarly in a different manufacturer's vaginal mesh litigation: "experts may not testify about what other parties did or did not know. However, to the extent [Defendant] seeks to exclude Dr. Rosenzweig's testimony about factual issues or the knowledge of the medical community in general, . . . [e]xpert witnesses may properly offer opinions on these topics." *In re Bos. Sci. Corp.*, 2018 WL 2426159 at *2. Gomez acknowledges Judge Goodwin's prior rulings as to corporate state of mind and states "Plaintiff will not offer Dr. Rosenzweig to testify as to AMS'[s] state of mind." (Doc. 120 at 12). The Court will thus grant AMS's motion to the extent that it seeks to exclude opinions regarding AMS's conduct, knowledge, or state of mind.

B. Medical Device Testing

AMS seeks to exclude Dr. Rosenzweig's opinions that "AMS 'failed to conduct adequate safety tests' on its mesh as it developed and sold its devices, including testing to determine if mesh degrades in the body and clinical trials prior to marketing its products and that the testing that AMS did perform was deficient." (Doc. 105 at 4). AMS argues Dr. Rosenzweig has no specialized training or education that qualifies him to offer such opinions. (Doc. 105 at 5). Gomez only counterargues that "Dr. Rosenzweig is qualified to render opinions regarding the adequacy of AMS' testing from perspective of a clinician based on his knowledge of and clinical experience with the risks of pelvic mesh products." (Doc. 120 at 10).

Judge Goodwin has repeatedly held Dr. Rosenzweig does not have the "experience, education, or knowledge about the appropriate testing that a medical device manufacturer should perform on its products prior to sale." *In re Bos. Sci. Corp. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2326, 2018 WL 2426159, at *2 (S.D.W. Va. May 29, 2018); *see also Griffin v. Bos. Sci. Corp.*, No. 2:13-cv-11876, 2016 WL 3031700, at *12 (S.D. W. Va. May 25, 2016) ("Dr. Rosenzweig lacks the experience and knowledge necessary to opine on what testing a manufacturer should perform on his products.").

Gomez fails to provide sufficient evidence of Dr. Rosenzweig's qualifications to opine on the adequacy of medical device testing. As such, AMS's motion will be granted to the extent it seeks to exclude Dr. Rosenzweig's opinions regarding the adequacy of device testing.

C. Medical Device Design and Warnings

AMS also seeks to exclude Dr. Rosenzweig's opinion that "AMS should have designed its polypropylene mesh implants differently." (Doc. 105 at 4; *see, e.g.*, Doc. 105 at 4–5 ("resin used to manufacture polypropylene pelvic mesh 'should never have been used in a medical implant' and '[t]he design of the Monarc . . . is inherently flawed' because of the risk of nerve damage and other complications; . . . '[t]he resin used to manufacture polypropylene mesh in MiniArc Products should never have been used to manufacture a medical implant.'")). AMS also seeks to exclude Dr. Rosenzweig's opinions that "AMS

should have provided additional warnings about the rate, severity, or duration of potential risks associated with its pelvic mesh." (Doc. 105 at 5; *see, e.g.*, Doc. 105 at 5 ("'AMS failed to disclose pertinent adverse risk information, pertinent information about the defects in the properties of the mesh.'")). As with device testing, AMS argues Dr. Rosenzweig has no specialized training or education that qualifies him to offer such opinions. (Doc. 105 at 5).

AMS reasons Dr. Rosenzweig's design opinions rely on his mesh degradation and contraction opinions, which are unqualified because he is not a biomaterials expert or pathologist. (Doc. 105 at 5). However, Judge Goodwin held at least four separate times that Dr. Rosenzweig's general causation testimony on mesh degradation and contraction based on the physical properties of polypropylene mesh are qualified and admissible. *See Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 565 (S.D. W. Va. 2014).

AMS specifically argues Dr. Rosenzweig is not qualified to opine about "the regulatory aspects of medical device warnings, including their adequacy vis-à-vis FDA regulations, or their development by device manufacturers in accordance with those regulations." (Doc. 105 at 2). Gomez makes clear Dr. Rosenzweig is not offered for those purposes;

> [Dr. Rosenzweig] is not proffered to render opinions on *how* AMS *developed* the warning in the IFUs that accompanied AMS' mesh devices. In addition, he is not offered to render opinions on the regulatory requirements or the method or process that is used to develop and approve warnings. Rather, Dr. Rosenzweig is opining as to the completeness and accuracy of the warnings and labels in the clinical setting of surgical treatment for incontinence and pelvic organ prolapse. His opinions are based on his knowledge, education, training and experience, his thorough review of the medical literature and Instructions for Use that he has reviewed.

(Doc. 120 at 5) (emphasis in original).

Judge Goodwin also made clear a physician's "experience *removing* polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him" "to opine on the design or adequacy of warnings of polypropylene transvaginal mesh devices." *Heatherly v. Bos. Sci. Corp.*, No. 2:13-CV-00702, 2018 WL 3797507, at *4 (S.D.

W. Va. Aug. 9, 2018) (emphasis in original). And Judge Campbell noted in a similar case, "Dr. Rosenzweig has decades of experience treating female urological conditions." *Triant v. Am. Med. Sys.*, No. CV-12-00450-PHX-DGC, 2020 WL 4333645, at *2 (D. Ariz. July 28, 2020). He has performed over a thousand pelvic floor surgeries. (Doc. 120 at 3). He has performed over 300 surgeries dealing with complications related to synthetic mesh, including numerous AMS device removals. (Doc. 120 at 3). He testified that his opinions are based on his clinical experience, a review of the relevant literature, years of explanting mesh from women with mesh complications, and AMS internal documents. (Doc. 120 at 3–4). He has also counseled more than a thousand patients undergoing pelvic floor surgeries, including hundreds involving mesh complications.

Based on his extensive gynecological experience, the Court finds Dr. Rosenzweig qualified to opine on medical device design and warnings and AMS's motion will be denied on this issue.

D. Alternative Design

AMS seeks to exclude Dr. Rosenzweig's opinions regarding "a number of 'feasible alternatives'" to AMS's mesh because none of the alternatives are "alternative pelvic mesh implant[s] available in the United States." (Doc. 105 at 6). In particular, AMS claims Dr. Rosenzweig's alternatives are either:

> surgical techniques . . . (the Burch procedure, suturing a sling made of the patient's own tissue, suturing a sling made of cadaveric tissue, suturing a patient's tissues together, or an abdominal sacralcolpopexy incorporating a polypropylene mesh graft), or they are products not approved or cleared for sale in the United States (the "Dynamesh" sling made of polyvinylidene difluoride or "PVDF"), or hypothetical products that do not exist ("mesh sling with less polypropylene and sealed edges" or "lighter weight, larger pore mesh sling [with] a shorter piece of mesh."

(Doc. 105 at 6–7). AMS argues these opinions will not help the jury "evaluate the safety and efficacy of AMS's pelvic mesh product designs." AMS also argues the alternative design opinions constitute "design opinions that exceed the scope of Dr. Rosenzweig's expertise." (Doc. 105 at 6).

But Dr. Rosenzweig is qualified to opine on device design. The question then is whether his alternative opinions are admissible because they are helpful to the jury. Judge Campbell deferred ruling on the same question in *Triant* until trial, but noted he was "inclined" to find "an alternative surgical procedure cannot be used to show a defective design of a product." *Triant*, 2020 WL 4333645, at *3. Judge Campbell also included a discussion of Arizona law:

> Whether this alternative design testimony is relevant will depend on the claims asserted by Plaintiffs under Arizona law – a topic to which the parties give scant attention. In *Golonka v. General Motors Corporation*, 65 P.3d 956 (Ariz. Ct. App. 2003), the Arizona Court of Appeals noted that a risk/benefit analysis may be used in design defect and strict liability cases, and that the factors to be considered by the jury include the usefulness and desirability of the product and the availability of other and safer products to meet the same need. *Id.* at 962 & n.2. . . . Plaintiffs have also asserted strict liability claims [], and it is possible that alternative procedures may be admitted to show that a product is unreasonably dangerous.

Id. Arizona's law provides a starting point but it does not yet directly address this question. The parties each cite cases from other jurisdictions in support of their positions. Again, AMS argues only available products, not procedures or unavailable products, are relevant to products liability. (Doc. 122 at 5–7). Gomez argues an effective substitute, including surgical procedures, is relevant. (Doc. 120 at 14–16). Presently, the Court is persuaded by the latter. The benefit of a product directly relates to its value compared to alternative options, including alternative procedures. *See, e.g.*, *Messina v. Ethicon*, No. 620CV1170ORL40LRH, 2020 WL 7419586, at *4 (M.D. Fla. Dec. 17, 2020) ("Dr. Rosenzweig's opinion that alternate medical procedures were safe and effective—that is, they are safer than the accused product and were feasible for [Plaintiff]—are relevant to demonstrating that the [product's] inherent risks outweigh its benefits.") (footnote omitted). And in any event, Dr. Rosenzweig will be subject to cross-examination. Accordingly, the Court will deny AMS's motion on this issue. Dr. Rosenzweig will be allowed to testify about alternative design opinions regarding alternative surgical procedures.

Separately, as was the case in *Triant*, the parties have not sufficiently briefed the question of whether hypothetical products or products not available in the United States are relevant and admissible. *See Triant*, 2020 WL 4333645, at *3 ("T]he Court [cannot] conclude at this stage that an alternative product cannot be cited unless it is licensed in the United States."). The Court will defer the issue for later consideration if appropriate. The AMS's motion on this issue is denied without prejudice.

E. Legal Conclusions

AMS also seeks to exclude Dr. Rosenzweig's opinions that "constitute improper legal conclusions." (Doc. 105 at 7). Gomez acknowledges "the scope of permissible expert testimony articulated by the MDL Court with respect to 'legal conclusions,'" and will "not [to] elicit legal conclusions from [her] experts." (Doc. 120 at 14) Accordingly, AMS's motion will be denied as moot on this issue.

F. Material Safety Data Sheet ("MSDS")

AMS seeks to exclude Dr. Rosenzweig's opinions "AMS products should not have incorporated polypropylene mesh because the manufacturer of the resin used in the mesh . . . included a . . . 'medical application caution' in its material safety data sheet [] stating that the material should not be permanently implanted in the human body." (Doc. 105 at 7). AMS also objects to Dr. Rosenzweig's suggestion that the MSDS should have led AMS to do different product testing. (Doc. 105 at 7).

Judge Goodwin held in a separate litigation, "[a] urogynecologist does not need to be an expert in crafting MSDS warnings to use the substance of such warnings in forming opinions about how mesh reacts in the human body." *In re Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2327, 2016 WL 8788207, at *4 (S.D. W. Va. Aug. 26, 2016). Judge Campbell similarly found Dr. Rosenzweig qualified to rely on the MSDS to support his opinion that the mesh at issue should not be used in the vagina. *Triant*, 2020 WL 4333645, at *4. Both parties acknowledge two additional cases where Dr. Rosenzweig was qualified to rely on the MSDS. (*See, e.g.*, Doc. 122 at 8–9). AMS provides no authority otherwise. The Court will allow Dr. Rosenzweig to rely on the MSDS as the basis for his

opinions and will deny AMS's motion on this issue.

G. Cancer

AMS seeks to exclude Dr. Rosenzweig's opinions about the possible association between cancer and polypropylene mesh, which he has not offered here but has in other pelvic mesh MDL cases. (Doc. 105 at 8). And Gomez will not offer such opinions from Dr. Rosenzweig. (Doc. 120 at 14). The motion is denied as moot on this issue.

II. Dr. Bruce Rosenzweig's Specific Causation Opinions

A. General Causation Opinions

AMS seeks to exclude all of Dr. Rosenzweig's specific causation opinions as based only on his general causation opinions which AMS contends are unreliable. (Doc. 65 at 2). Gomez notes, Dr. Rosenzweig relies on, in addition to his general causation opinions, deposition materials, medical records, scientific literature, and corporate documents to form his specific causation opinions. (Doc. 84 at 4). As held above, Dr. Rosenzweig's general causation opinions are essentially qualified and reliable. As such, AMS's motion will be denied on this issue.

B. Degradation and Contraction

AMS seeks to exclude Dr. Rosenzweig's opinions that degradation and contraction of Gomez's mesh caused her injuries as without reliable foundation that the mesh actually degraded or contracted. (Doc. 65 at 3–4). AMS complains that Dr. Rosenzweig, a urologist, has not examined any pathology specimens from Gomez's explant procedures, such that his opinions are mere speculation and without evidentiary support. (Doc. 65 at 3–4).

Gomez was first implanted with a MiniArc device. That device was explanted and replaced with a Monarc device. The Monarc appears to remain implanted. (*See* Doc. 84-1 at 36).

AMS does admit Dr. Rosenzweig has evidence that Gomez's MiniArc degraded and contracted. According to Dr. Rosenzweig, a new MiniArc device is 1 to 1.1 centimeters wide, but the device was only 0.5 centimeters wide when explanted from Gomez. (Doc. 84 at 7). Dr. Rosenzweig opines this is evidence of "contraction, deformation, degradation,

roping, and curling." (Doc. 84 at 7). AMS does not dispute this but claims because this is Dr. Rosenzweig's only evidence of degradation and contraction, the opinion is inadmissible. (Doc. 99 at 3). AMS also claims its expert and other medical records show no signs of degradation. (Doc. 99 at 3). However, that goes to weight, not admissibility, and Dr. Rosenzweig's opinion will be allowed.

AMS also states Dr. Rosenzweig has no evidence of degradation or contraction of Gomez's Monarc device, as Gomez's Monarc device remains in her body. (Doc. 99 at 3, 22). Dr. Rosenzweig obviously cannot opine on the Monarc's present and actual degradation or contraction. However, Dr. Rosenzweig will be allowed to testify to the likelihood of contraction or degradation of the Monarc device to the extent possible without the specimen having been observed, as discussed in the next section. Accordingly, AMS's motion will be denied on this issue.

C. Opinions Regarding Defectiveness and Causation

AMS seeks to exclude Dr. Rosenzweig's opinion that the mesh products were defective and caused Gomez's injury because his differential diagnosis is unreliable. (Doc. 65 at 5). A differential diagnosis "is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1057 (9th Cir. 2003), *as amended on denial of reh'g* (Sept. 25, 2003) (citation and internal quotation marks omitted). "[A] reliable differential diagnosis passes muster under *Daubert*." *Id.* at 1058.

AMS claims, unlike an arguably typical differential diagnosis, Dr. Rosenzweig did not conduct a physical exam and only reviewed Gomez's medical history. (Doc. 65 at 5). AMS contends Dr. Rosenzweig's opinion is based on "little more than timing—that Ms. Gomez's complaints followed an implant procedure" and thus "succumb to the logical fallacy of *post hoc ergo propter hoc*." (Doc. 65 at 5 (citation and internal quotations omitted)).

A physical exam is not always necessary to reach a differential diagnosis. "A doctor using a differential diagnosis grounded in significant clinical experience and examination

of medical records and literature can certainly aid the trier of fact." *Messick v. Novartis Pharm.*, 747 F.3d 1193, 1199 (9th Cir. 2014).

In fact, Dr. Rosenzweig reliably ruled out or found other causes less likely after Gomez's fibroids, ovarian cysts, adenomyosis, and the ovaries that stimulate endometriosis were removed and pain persisted. (Doc. 84 at 7). And Dr. Rosenzweig relied on the evidence of degradation and contraction to support his opinion. (Doc. 84 at 7). Dr. Rosenzweig's opinion was based on his clinical experience, an examination of the medical records, and the literature. (Doc. 65-1 at 19).

Whether Dr. Rosenzweig's opinion is persuasive after cross-examination will be determined at trial. The Court finds Dr. Rosenzweig's opinion that the mesh products were defective and caused Gomez's injuries are reliable and the motion will be denied on this issue.

D. Future Harm

AMS seeks to exclude Dr. Rosenzweig's opinions that Gomez may have future symptoms and complications as speculation. (Doc. 65 at 6). Gomez identifies the evidence Dr. Rosenzweig relied upon as medical records and deposition testimony that includes that Gomez's pain is chronic and ongoing, which is reliable enough to be presented to the jury and his opinions will be the subject of cross-examination. (Doc. 84 at 8). The Court will deny AMS's motion on this issue.

III. Dr. Vladimir Iakovlev's Opinions

AMS seeks to exclude the general causation opinions of Dr. Vladimir Iakovlev, an anatomical pathologist. (Doc. 68 at 2). AMS does not challenge Dr. Iakovlev's qualification.

A. General Causation

AMS seeks to exclude Dr. Iakovlev's general causation opinions because of the methodologies and the scientific literature he relies upon are unreliable. (Doc. 68 at 2). Judge Goodwin has repeatedly found Dr. Iakovlev's methodologies related to his mesh studies unreliable. For example, Judge Goodwin reasoned:

> Dr. Iakovlev's general causation opinions are based largely on his examination of the mesh explant samples in his personal data pool. However, Dr. Iakovlev provides no information on how the mesh explants were chosen or prepared for examination. Indeed, Dr. Iakovlev testified that plaintiffs' counsel provided approximately seventy percent of the transvaginal mesh explants, but he does not know how those explants were chosen or what methodology counsel employed.

In re Bos. Sci. Corp. Pelvic Repair Sys. Prod. Liab. Litig., No. MDL 2326, 2018 WL 2419058, at *2 (S.D.W. Va. May 30, 2018). Judge Goodwin has also excluded Dr. Iakovlev's opinions for lack of sample size, error rate, written protocol, and standardized methodology. *See, e.g.*, *Edwards v. Ethicon*, No. 2:12-CV-09972, 2014 WL 3361923, at *23 (S.D.W. Va. July 8, 2014).

Here, Dr. Iakovlev's specimens are from his hospital, referring hospitals, and medico-legal consultations. (Doc. 68-1 at 7). He received about 60 specimens, almost all related to this MDL. (Doc. 68 at 5). He does not know how mesh specimens were selected. (Doc. 68 at 4). Some were pre-stained, others he stained himself. (Doc. 68 at 4). Dr. Iakovlev's report then only included specimens which demonstrated scarring or foreign body response. (Doc. 68 at 5). He had no standardized process for obtaining, preparing, or selecting specimens for inclusion in his report. (Doc. 68 at 4). He did not use a control group, instead he referenced samples "embedded in [his] head." (Doc. 68 at 5). He failed to track which specimen photographs captured. (Doc. 68 at 5). When presented with photographs during his deposition, Dr. Iakovlev could not replicate the results in his report. (Docs. 68 at 5; 99 at 5). As the Judge Goodwin repeatedly held, Dr. Iakovlev's opinions cannot be reliable because he provides no reliable methodology to support his conclusions.

With regard to the Dr. Iakovlev's "stretch test," Judge Goodwin found it unreliable because Dr. Iakovlev failed to standardize his method or results and conducted the test outside of the body, which is not sufficiently similar to the way mesh would exist within the body. *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 709–10 (S.D.W. Va. 2014). The Court agrees and Dr. Iakovlev's opinions will be excluded to the extent they rely on

his study of AMS mesh specimens and the "stretch test." The motion will be granted.[6]

AMS also seeks to preclude all other experts from relying on Dr. Iakovlev's unreliable opinions. (Doc. 68 at 10). Presently, other experts will not be allowed to rely on Dr. Iakovlev's opinions and bases to the extent they have been found unreliable here. The parties give scant and insufficient attention to other opinions relying upon Dr. Iakovlev's opinions, so the motion is denied without prejudice on this issue.

IV. Dr. Jerry Blaivas's Opinions[7]

AMS seeks to exclude the specific causation opinions and testimony of Dr. Jerry Blaivas because it argues his methods are unreliable and he is not qualified to offer these opinions. (Doc. 73 at 1–2). AMS specifically seeks exclusion of improper legal conclusions, opinions about AMS's state of mind, opinions that AMS did not adequately test its products and did not provide adequate warning with the products, and opinions about the "degradation" and "shrinkage" of AMS's mesh. (Doc. 73 at 2–3).

Dr. Blaivas is a urologist, who teaches medicine and practices surgery in Massachusetts and New York. (Doc. 73-1 at 3). Dr. Blaivas helped develop the techniques for sling surgery for women suffering incontinence. (Doc. 73-1 at 3). He has experience implanting and explanting both autologous and synthetic slings. (Doc. 73-1 at 3–4).

A. Mesh Degradation

AMS argues Dr. Blaivas is not qualified to opine that polypropylene mesh degrades *in vivo* and is subject to degradation and deformation, which causes pain, contracture, and other complications because he lacks specialized knowledge in biomedical engineering and biomaterials.[8] (Doc. 73 at 3). In response, Gomez provides Dr. Blaivas' credentials. He is a board-certified clinical and academic urologist and has performed around 1,500 procedures to treat stress urinary incontinence, pelvic organ prolapse, or both. (Doc. 80 at 3–4). Most often, Dr. Blaivas used autologous tissue in these procedures, but he also

[6] Because the motion is granted on the unreliability of Dr. Iakovlev's study, the Court will not address Dr. Iakovlev's reliance on scientific literature.

[7] AMS may have attempted to file a reply regarding Dr. Blaivas but filed its reply for Dr. Rosenzweig's specific causation opinions a second time. (Doc. 97).

[8] AMS claims that Dr. Blaivas agreed he is unqualified to opine on the subject and admitted all his information comes from Gomez's expert, Dr. Iakovlev, but this is false. (Docs. 73 at 3; 73-2 at 29).

implanted around twelve synthetic mesh slings and explanted over 100 mesh slings. (Docs. 80 at 4; 80-1 at 4). Like Dr. Rosenzweig, Dr. Blaivas' clinical and professional experience qualifies him to opine about vaginal mesh and its complications. What he lacks in expertise in biomedical engineering goes to the weight of his testimony, not the admissibility. *See United States v. Garcia*, 7 F.3d 885, 890 (9th Cir. 1993) ("lack of particularized expertise goes to the weight accorded [the expert's] testimony, not to the admissibility of [their] opinion as an expert"). AMS's motion will be denied on this issue.

B. Device Design

AMS seeks to exclude Dr. Blaivas' opinion that AMS's mesh devices "should not have been designed for placement in a surgically contaminated field" because he is unqualified to opine on the design of mesh devices. (Doc. 73 at 4). AMS argues Dr. Blaivas' criticism of the transvaginal surgical approach does not equate to relevant experience in device design, he has never designed a medical device to treat stress urinary incontinence or pelvic organ prolapse, and he has never designed a mesh device. (Doc. 73 at 4). In response, Gomez cites Dr. Blaivas' years of experience with gynecological surgeries and surgical fields. (Doc. 80 at 6). As mentioned above, Dr. Blaivas has implanted around twelve synthetic mesh slings and explanted over 100 mesh slings. (Docs. 80 at 4; 80-1 at 4). Although Dr. Blaivas does not have experience with mesh design, his extensive experience with gynecological surgery including at least 100 mesh explant procedures qualifies him to opine about device design. A surgeon's opinion may be less valuable than a biochemical engineer's but that does not disqualify the surgeon. As with Dr. Rosenzweig, Dr. Blaivas is qualified to offer this opinion and AMS's motion will be denied on this issue.

C. Device Testing

AMS seeks to exclude Dr. Blaivas' opinion that AMS did not perform adequate testing on its mesh products because he is unqualified to opine on appropriate testing for mesh devices. (Doc. 73 at 4–5). Gomez concedes the point. (Doc. 80 at 2 n.1). AMS's motion will be denied as moot.

D. Device Marketing

AMS seeks to exclude Dr. Blaivas' opinion that "synthetic slings were revived,

reinvented and promoted by industry through pervasive advertising inducements to physicians to perform such surgeries" because he is unqualified to offer "marketing" opinions. (Doc. 73 at 5). Gomez concedes the point. (Doc. 80 at 2 n.1). AMS's motion will be denied as moot on this issue.

E. Mesh Complication Rate

AMS seeks to exclude Dr. Blaivas' opinion that "the overall risk of a negative outcome after SMUS implantation surgery is greater than or equal to 15 percent" because the opinion is speculative and unreliable. (Doc. 73 at 5). AMS argues Dr. Blaivas admits the complication rate is imprecise. (Doc. 73 at 5–6). But Dr. Blaivas explains the reason this calculus is imprecise, that is, underreporting is well-documented. (Doc. 73-1 at 15). Dr. Blaivas' findings were published in Nature Reviews Urology, a peer-reviewed publication. (Doc. 73-1 at 15; Nature Research: Peer-review policy, https://www.nature.com/nature-research/editorial-policies/peer-review#selecting-peer-reviewers (last accessed December 1, 2020)). These findings may be used where relevant to challenge his opinion, but AMS did not do so.[9] Instead, AMS quotes Dr. Blaivas' deposition in which he explains the imprecise nature of calculating complication rates. (Doc. 73 at 5–6). Because AMS does no more than summarily allege unreliable methods, AMS's motion will be denied on this issue.

F. Warnings

AMS seeks to exclude Dr. Blaivas' opinion that the mesh "should not have been designed for placement in a surgically contaminated field . . . without a clear warning about the possibility of short and long term complications" and that the Monarc (a particular mesh product) Instructions for Use ("IFU") did "not even mention the severity and life style altering nature of some of these complications" because he is not a regulatory expert and the opinions are unreliable. (Doc. 73 at 6). Judge Goodwin recognized Dr. Blaivas, as a urologist, is qualified to testify about the risks of devices and whether IFUs adequately express those risks. *Huskey v. Ethicon*, 29 F. Supp. 3d 691, 719 (S.D.W. Va. 2014). The

[9] Again, rather than file a reply relevant to this motion, AMS appears to have filed its reply to the Dr. Rosenzweig specific causation motion twice. (Doc. 97).

Court agrees and AMS's motion will be denied on the issue.

G. Corporate State of Mind

Finally, AMS seeks to exclude Dr. Blaivas' opinions that AMS "knew" or "should have known" about complications with its devices and those of its competitors because of problems associated with predicate devices as "state of mind" testimony. (Doc. 73 at 7). Gomez concedes the issue. (Doc. 80 at 2 n.1). AMS's motion will be denied as moot on this issue.

V. Drs. Scott Guelcher and Jimmy Mays' Opinions

AMS moves to exclude Drs. Scott Guelcher and Jimmy Mays' general causation opinions, "state of mind" opinions, and legal conclusions. (Doc. 75 at 2). Additionally, AMS seeks to exclude Dr. Guelcher's opinions on proposed alternative designs and the adequacy of AMS's testing on its pelvic mesh devices. (Doc. 75 at 2).

Dr. Guelcher holds a Ph.D. in chemical engineering and a post-doctoral degree in biomedical engineering. (Doc. 75-1 at 1). He is currently a professor of chemical and biomolecular engineering. (Doc. 75-1 at 1). Dr. Mays has a Ph.D. in Polymer Science and worked for four years as a research chemist for a manufacturer of polypropylene. (Doc. 75-2 at 2–3). He is currently a professor of chemistry and scientist at the Oak Ridge National Laboratory. (Doc. 75-2 at 2).

A. In Vivo Degradation

AMS seeks to exclude as unreliable Drs. Guelcher and Mays' opinions that mesh degrades *in vivo*. (Doc. 75 at 5). Central to AMS's argument is the fact that *in vivo* mesh degradation is "merely a hypothesis in need of further study." (Doc. 75 at 5). The parties primarily dispute whether the methods in the proverbial "Talley study" (also known as "Oxidation and degradation of polypropylene transvaginal mesh" found in the 2017 Polymer Edition of the Journal of Biomaterials Science). (Doc. 75 at 6–7). The study was subject to peer-review and published. (Doc. 83 at 5). AMS accuses the Talley study of lacking any protocol. (Doc. 75 at 8). Yet, the Talley study contains a detailed materials and methods section, which AMS fails to address. (Doc. 75-3 at 5–7). AMS criticized the study for its small sample size and the materials used, none of which were AMS mesh. (Doc. 96

at 3). But Drs. Guelcher and Mays seek to use this study to support their opinion that polypropylene mesh, generally, degrades *in vivo*. The details of the study go to weight, not admissibility of the opinions. In short, the Court finds no reason to find the Talley study unreliable as a matter of law. AMS's motion will be denied on this issue.

AMS also argues other studies relied upon are flawed as only putting forth hypotheses in need of further study. (Doc. 75 at 8). However, the studies highlighted by AMS provide evidence to support the hypothesis that mesh degrades *in vivo*. *See*, *e.g.*, Materials Characterization of Explanted Polypropylene Hernia Meshes (Doc. 82-7 at 2) ("Overall, the results supported our hypothesis that oxidation is involved with the degradation of polypropylene hernia mesh materials."). Moreover, all the studies are published in peer-reviewed publications. (Doc. 83 at 3–4). AMS "is right that none of the studies establish all aspects of [Drs. Guelcher and Mays'] opinions, which is why [their] report is necessary to connect them." *Zeiger v. WELLPET*, No. 3:17-CV-04056-WHO, 2021 WL 756109, at *6 (N.D. Cal. Feb. 26, 2021). A study admitting a hypothesis requires further study does not make it unreliable. Offering a hypothesis as an opinion goes to weight, not admissibility, so long as there is support in objective evidence. AMS does not argue there is *no* support for these theories. The concerns AMS has with the studies can be addressed on cross-examination, as AMS demonstrated in its deposition of Dr. Mays. (Doc. 75-3 at 7). Experts may hypothesize "so long as [the expert] relied upon a variety of objective, verifiable evidence." *Clausen*, 339 F.3d at 1060–61. AMS's motion will be denied on this issue.

AMS again notes that many of the authors of these studies are Gomez's designated experts in this litigation, limiting their independence and credibility. (Doc. 75 at 5). However, several of the articles' authors are not experts in vaginal mesh cases, providing evidence of some independence and credibility. Again, an accusation of bias is an issue for cross-examination.

B. Medical Causation

AMS seeks to exclude Drs. Guelcher and Mays' opinions that *in vivo* degradation of mesh causes pain, scarring, and inflammation because they are not medical doctors.

(Doc 75 at 9). Both Drs. Guelcher and Mays have strong credentials in polymer science. Much of their research looks at effects of polypropylene in the body. Their review of the literature led to their opinions that *in vivo* degradation can cause negative effects in the body. (E.g., Doc. 75-1 at 18). As chemists and engineers, they are qualified to opine that "mesh is not inert and its properties change after implantation, which can lead to adverse events in the implantee." (Doc. 83 at 6). However, they are not medical professionals, have not examined patients, and have not conducted differential diagnoses. Thus, as Judge Goodwin held, they are unqualified to offer opinions regarding the medical complications that mesh degradation can cause. *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4547055, at *3 (S.D.W. Va. Aug. 31, 2016). To the extent Gomez attempts to offer Drs. Guelcher and Mays for their opinions regarding medical complications, AMS's motion will be granted.

C. Improper Legal Conclusions

AMS argues Guelcher and Mays' opinions that AMS created an "unreasonable risk" of oxidation and degradation and that the products are "unreasonably dangerous" and "defective" are improper legal conclusions. (Doc. 75 at 9). Gomez agrees that Drs. Guelcher and Mays will not testify to any improper legal conclusions. (Doc. 83 at 7). Accordingly, AMS's motion will be denied as moot on this issue.

D. Corporate State of Mind

AMS argues Guelcher and Mays' expert report speculates as to AMS's state of mind, intent, knowledge, and corporate conduct. (Doc. 75 at 10). Gomez agrees Drs. Guelcher and Mays will not testify to AMS's knowledge, state of mind, or corporate conduct. (Doc. 83 at 7). AMS's motion will be denied as moot on this issue.

E. Safer Alternative Design Opinions

AMS argues Dr. Guelcher does not offer proper a safer alternative design because he only proposes alternative surgeries or procedures, not products. (Doc. 75 at 10–11). As discussed above with regard to Dr. Rosenzweig, safer alternative surgeries or procedures are permissible and relevant to the Arizona state benefit/risk analysis for products liability. According, AMS's motion will be denied on this issue.

F. Testing Opinions

AMS seeks to exclude Dr. Guelcher's opinions that AMS failed to perform adequate testing on its pelvic mesh device. (Doc. 75 at 11). AMS argues that Dr. Guelcher is "neither a medical doctor nor a medical device engineer." (Doc. 75 at 11). (Doc. 73 at 4–5). AMS claims Dr. Guelcher "has no experience in designing or testing medical devices." (Doc. 75 at 11). Gomez failed to respond to this argument. As such, AMS's motion will be granted on this issue.

VI. Dr. Debora Joslin's Opinions[10]

Gomez seeks to exclude Dr. Debora Joslin's opinions. Dr. Joslin has a Ph.D. in Metallurgical Engineering and is a research scientist, with expertise in electron beam microanalysis. (Doc. 92 at 3).

A. Reliance on Wayne Niemeyer's Reports

Gomez seeks to strike Wayne Niemeyer's testing reports, on which Dr. Joslin relied, because he is not an expert in this case. (Doc. 71-1 at 2). If the Court agrees, Gomez then seeks to exclude all of Dr. Joslin's opinions because they lack support without Mr. Niemeyer's reports. (Doc. 71-1 at 2). Federal Rule of Evidence 703 does not require an expert to create their own data. Rather, it allows an expert to rely on data "the expert has been made aware of . . . [that] experts in the particular field would reasonably rely on." Fed. R. Evid. 703. Dr. Joslin reached her conclusions "based on [her] review of the original data." (Doc. 92 at 5). There is nothing in the record to establish this is data an expert would not reasonably rely on. (Doc. 71-1 at 3–4). Accordingly, Gomez's motion will be denied on this issue.

B. Reliance on Mr. Niemeyer's Data and Methodology

Gomez seeks to exclude Dr. Joslin's opinions because "she did not perform an independent analysis and instead merely adopted Mr. Niemeyer's work without any knowledge of the underlying methods." (Doc. 71-1 at 6). Dr. Joslin testified repeatedly the analysis was her own. (Doc. 92 at 5). The Court finds no evidence to the contrary.

[10] Gomez failed to file a reply related to her motion to exclude Dr. Joslin's opinions.

As to Mr. Niemeyer's methodologies, Gomez again argues the report lacks reliability. (Doc. 71-1 at 5–6). The findings and conclusions in Mr. Niemeyer's report go to weight, not admissibility. Any problems with the underlying data will be subject to cross-examination. As such, Gomez's motion will be denied on this issue.

C. Manufacturing Process and Testing

Gomez seeks to exclude Dr. Joslin's opinions as unqualified regarding the manufacturing process and Niemeyer's testing process. Gomez argues Dr. Joslin is not familiar with the manufacturing process of mesh. (Doc. 71-1 at 10.) AMS agrees it will not have Dr. Joslin opine about the manufacturing process. (Doc. 92 at 7 n.23). Accordingly, Gomez's motion will be denied as moot on this issue..

Gomez also argues Dr. Joslin is not an expert in the analytical tests conducted by Mr. Niemeyer. (Doc. 71-1 at 10). However, Dr. Joslin is specifically an expert in the type of microscopy that Mr. Niemeyer used in his testing. As such, Gomez's motion will be denied on this issue.

D. Discovery Violations

Gomez seeks to exclude Dr. Joslin's opinions for an alleged discovery violation. Discovery was completed at the MDL stage. (Doc. 71-1 at 10). Gomez alleges Dr. Joslin failed to produce the underlying data and notes she reviewed in support of her expert report. (Doc. 71-1 at 10). The proper vehicle for a discovery dispute is a discovery motion, not a *Daubert* motion. As discovery and its disputes have long been closed, Gomez's motion will be denied on this issue.[11]

VII. Dr. Karen Becker's Opinions

Gomez seeks to exclude Dr. Karen Becker's expert opinions because they relate to the FDA's 510(k) process. Both parties agree Judge Goodwin repeatedly found this type of testimony excludable as unrelated to safety or efficacy. (Doc. 110 at 3). *See*, *e.g.*, *Lewis v. Johnson & Johnson*, 991 F.Supp.2d 748, 753–56 (S.D.W. Va. 2014). This is best resolved on a motion for limine, although the parties appear open to a stipulation on the

[11] If at trial it is learned that AMS has failed to produce the material data requested, the Court will consider sanctions.

matter. (Doc. 110 at 3). Accordingly, the Court will deny Gomez's motion without prejudice. The Court encourages the parties to discuss a stipulation on such testimony.

VIII. Dr. Stephen Badylak's Opinions

Gomez seeks to exclude Dr. Stephen Badylak's opinions as unreliable and unqualified. (Doc. 107 at 2). Dr. Badylak has degrees in medicine, pathology, and veterinary medicine and specializes in biomaterials and tissue scaffolds such as surgical mesh. (Doc. 109 at 3).

A. Contradictory Research

Gomez seeks to exclude all of Dr. Badylak's opinions as contradicted by his own prior research rendering them unreliable. (Doc. 107 at 4). Specifically, Gomez asserts Dr. Badylak's prior research supports the hypothesis that polypropene mesh can wrinkle and degrade after implantation, which can lead to complications. (Doc. 107 at 3). The Court agrees with Judge Goodwin that "[a]lleged inconsistencies in a witness's testimony go to credibility, rather than Daubert's standard of admissibility." *Wise v. C.R. Bard*, No. 2:12-CV-01378, 2015 WL 521202, at *13 (S.D.W. Va. Feb. 7, 2015) (citation and internal quotation marks omitted). The credibility of Dr. Badylak's opinions are best addressed through cross-examination. Accordingly, Gomez's motion will be denied on the issue.

B. Steady State Foreign Body Reaction

Gomez seeks to exclude Dr. Badylak's opinions regarding a steady state foreign body reaction to mesh because he fails to cite specific research but instead relies on his own experience and the entire body of available literature. (Doc. 107 at 5). Gomez also states a publication referenced by Dr. Badylak in his deposition contradicts his opinion and is not cited in his expert report. (Doc. 107 at 7). Looking to Dr. Badylak's deposition, he extensively explains the research he relies on, including citing specific publications to support his opinions. (Doc. 107-2 at 158–166; *see*, *e.g.*, "Well, there are several studies. . . . probably the most convincing early set of studies was conducted by Jim Anderson."). With regard to the allegedly contradictory publication, Gomez is mistaken that Dr. Badylak fails to cite the publication he references in his deposition. (Doc. 109-2 at 3). And Dr.

Badylak does not rely on the publication Gomez accuses Dr. Badylak of relying upon to form an opinion contradictory to the publication. Gomez is engaging in cross-examination by paper, nothing else. Accordingly, Gomez's motion will be denied on this issue.

C. Toxicity, Design, and Resin

Gomez seeks to exclude Dr. Badylak's toxicity, design, and resin opinions as unqualified or unreliable. (Doc. 107 at 8). It is unclear whether Gomez is challenging Dr. Badylak's qualifications or methodology. Gomez asserts these opinions "exceed his expertise" without ever addressing his qualifications or the qualifications required. As such, the Court will only address Dr. Badylak's methodology. Gomez states the opinions are "not based in testing, literature or other reliable means." (Doc. 107 at 8). AMS responds by putting forth the biocompatibility and toxicity testing, as well as peer-reviewed literature, Dr. Badylak relied upon. (Doc. 109 at 10). In her reply, Gomez then argues the testing completed does not prove the biocompatibility of AMS's products. (Doc. 111 at 5). Gomez does not argue the testing conducted was unreliable.

AMS has shown Dr. Badylak's opinions have enough reliable support to be presented to the jury. The extent of that support can be best addressed on cross-examination. Thus, Gomez's motion will be denied on this issue.

D. Corporate State of Mind

Gomez seeks to exclude Dr. Badylak's opinions that opine as to AMS's state of mind or intent. (Doc. 107 at 9). Although AMS asserts, Dr. Badylak did not offer any state of mind opinions, AMS agrees that state of mind opinions should generally be excluded. (Doc. 109 at 11). Moreover, the MDL Court excluded Dr. Badylak's opinions, similar to the testimony offered here, as a corporate state of mind opinion. *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501, 576 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014). Gomez's motion will be denied as moot on this issue.

This matter is now ready for trial. Accordingly,

IT IS ORDERED AMS's motion to limit the general causation opinions and testimony of Bruce Rosenzweig, MD (Doc. 104) is **GRANTED IN PART** and **DENIED**

IN PART. Dr. Rosenzweig's general causation opinions will be excluded to the extent the motion seeks to exclude opinions regarding AMS's conduct, knowledge, or state of mind and opinions regarding the adequacy of device testing.

IT IS FURTHER ORDERED AMS's motion to exclude specific causation opinions and testimony of Bruce Rosenzweig MD (Doc. 61) is **DENIED**.

IT IS FURTHER ORDERED AMS's motion to exclude testimony of Vladimir Iakovlev MD (Doc. 67) is **GRANTED**. Dr. Iakovlev's opinions will be excluded.

IT IS FURTHER ORDERED AMS's motion to exclude the specific causation opinions and testimony of Jerry Blaivas MD (Docs. 72) is **DENIED**.

IT IS FURTHER ORDERED AMS's motion to exclude the opinions and testimony of Scott Guelcher PhD and Jimmy Mays PhD (Doc. 74) is **GRANTED IN PART** and **DENIED IN PART**. Drs. Guelcher and Mays' opinions will be excluded to the extent the motion seeks to exclude opinions regarding medical complications mesh degradation may cause and opinions about AMS's testing.

IT IS FURTHER ORDERED Gomez's motion to exclude the testimony of Debora L. Joslin, Ph.D (Doc. 70) is **DENIED**.

IT IS FURTHER ORDERED Gomez's motion to exclude the opinions and testimony of Karen Becker, PH.D. (Doc. 106) is **DENIED**.

IT IS FURTHER ORDERED Gomez's motion to exclude the opinions and testimony of Dr. Stephen F. Badylak, DVM, PH.D., M.D. (Doc. 107) is **DENIED.**

IT IS FURTHER ORDERED the pretrial deadlines set in the Court's January 8, 2021 Order (Doc. 108) are **VACATED**.

IT IS FURTHER ORDERED all Motions in Limine are due **April 6, 2021**. Responses are due seven days afterward. No replies are permitted unless ordered by the Court. Prior to filing any Motion in Limine, the parties must confer and discuss the contents of each planned motion. No Motion in Limine should be filed if the other party does not oppose the relief requested.

IT IS FURTHER ORDERED the Joint Proposed Pretrial Order, if not already

filed, is due **April 6, 2021**.

IT IS FURTHER ORDERED the parties shall review the Court's standard Juror Questionnaire (available on the Court's website) and submit **NO MORE THAN FIVE STANDARD PROPOSED QUESTIONS EACH** to be added to the standard Juror Questionnaire with the Court's approval no later than **April 6, 2021**. Each proposed question shall stand alone and shall not contain sub-parts.

IT IS FURTHER ORDERED the parties shall submit a Joint Statement of the Case, of no more than a few short sentences for the Juror Questionnaire, no later than **April 6, 2021**.

IT IS FURTHER ORDERED the parties shall submit a second Joint Statement of the Case, of no more than two short paragraphs to be read to the jury, no later than **April 20, 2021**.

IT IS FURTHER ORDERED no later than **April 20, 2021**, the parties shall file and submit via email (silver_chambers@azd.uscourts.gov) in Word format proposed Jury Instructions in compliance with the procedures available on the Court's website, including but not limited to: 1) a *joint* set of proposed jury instructions where the parties' instructions agree; 2) a separate set of instructions (one for each party) where the parties do not agree; and 3) legal authority supporting all proposed instructions whether the parties agree or not. Where the parties do not agree, the opposing party shall clearly state its objection to the proposed instruction and the proposing party shall clearly state its response.

IT IS FURTHER ORDERED the parties will jointly file a proposed form of verdict, or if the parties do not agree, they may separately file proposed forms of verdict no later than **April 20, 2021**.

IT IS FURTHER ORDERED no later than **April 20, 2021**, the parties shall deliver to chambers excerpts of the deposition testimony they propose to present at trial, in compliance with the procedures available on the Court's website (found in Deposition Designation Procedure for Judge Silver), including but not limited to: Plaintiffs highlighting in yellow the portions they wish to offer and Defendants highlighting in blue

those portions they wish to offer. If either party objects to the proposed testimony, a specific and concise objection (e.g., "Relevance, Rule 402") shall be placed in the margin adjacent to the proposed testimony.

IT IS FURTHER ORDERED a final pretrial conference is set for **May 11, 2021 at 11:00 a.m.**, at which time the Court will review Juror Questionnaires. The parties shall meet and confer prior to this date regarding the Juror Questionnaires and email to the Courtroom Deputy no later than noon on **May 10, 2021** a list of any jurors they agree should be stricken for cause, along with any objections to jurors they do not agree should be stricken for cause. **The parties shall not file this list.** The Court will rule on any disputed jurors at the final pretrial conference.

The parties will be supplied a disk containing the questionnaires approximately one week prior to the final pretrial conference. Counsel shall bring a copy of the questionnaires to the conference for review. Counsel are required to return the disk to the Courtroom Deputy and destroy all copies of the questionnaires no later than the last day of trial.

IT IS FURTHER ORDERED trial to a jury is set for **May 18, 2021 at 8:30 a.m.** Estimated length of trial is 10 days.

IT IS FURTHER ORDERED the parties shall comply with the Exhibit Procedures found on the Court's website at www.azd.uscourts.gov / Judges' Information / Orders, Forms & Procedures for Hon. Roslyn O. Silver.

Dated this 26th day of March, 2021.

Honorable Roslyn O. Silver
Senior United States District Judge